

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 23

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte LILIP LAU, WILLIAM M. HARTIGAN and JOHN J. FRANTZEN

Appeal No. 2002-1403
Application No. 09/323,783

ON BRIEF¹

Before ABRAMS, STAAB, and NASE, Administrative Patent Judges.
NASE, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 25 to 37, which are all of the claims pending in this application.

We REVERSE.

¹ We note that the appellants were unable to attend the oral hearing scheduled for February 19, 2003, however under the circumstances a hearing is not considered necessary. See 37 CFR § 1.194(c), last sentence.

BACKGROUND

The appellants' invention relates to a method of implanting a stent in a body lumen. A copy of the dependent claims under appeal is set forth in the appendix to the appellants' brief. Claims 25 and 29, the independent claims under appeal, read as follows:

25. A method of implanting a stent in a body lumen, comprising the steps of
(a) providing a stent;
(b) mounting the stent on a balloon of a balloon catheter;
(c) partially inflating the balloon to secure the stent onto the balloon;
(d) advancing the catheter, including the balloon and stent, through the body lumen;
(e) positioning the balloon and stent at a desired location in the body lumen;
(f) expanding the balloon, thereby deploying the stent at the desired location;
(g) deflating the balloon; and
(h) removing the catheter from the body lumen, whereby the stent remains deployed at the desired location in the body lumen.
29. A method of implanting a stent in a body lumen, comprising the steps of:
(a) providing a stent;
(b) mounting the stent on an expandable member of a delivery catheter;
(c) partially expanding the expandable member of the delivery catheter to secure the stent onto the expandable member;
(d) advancing the catheter, including the expandable member and stent, through the body lumen;
(e) positioning the expandable member and stent at a desired location in the body lumen;
(f) expanding the expanding member, thereby deploying the stent at the desired location;
(g) contracting the expandable member; and
(h) removing the catheter and expandable member from the body lumen, whereby the stent remains deployed at the desired location in the body lumen.

The prior art references of record relied upon by the examiner in rejecting the appealed claims are:

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|-----------|-----------|---------------|
| Schatz | 5,195,984 | Mar. 23, 1993 |
| Hillstead | 5,476,476 | Dec. 19, 1995 |

Claims 25, 26 and 29 to 31 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Schatz.

Claims 27, 28 and 32 to 37 stand rejected under 35 U.S.C. § 103 as being unpatentable over Schatz in view of Hillstead.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellants regarding the above-noted rejections, we make reference to the final rejection (Paper No. 8, mailed March 16, 2001) and the answer (Paper No. 14, mailed November 16, 2001) for the examiner's complete reasoning in support of the rejections, and to the brief (Paper No. 13, filed September 24, 2001) and reply brief (Paper No. 16, filed February 15, 2002) for the appellants' arguments thereagainst.

OPINION

In reaching our decision in this appeal, we have given careful consideration to the appellants' specification and claims, to the applied prior art references, and to the

respective positions articulated by the appellants and the examiner. As a consequence of our review, we make the determinations which follow.

The anticipation rejection

We will not sustain the rejection of claims 25, 26 and 29 to 31 under 35 U.S.C. § 102(e) as being anticipated by Schatz.

Schatz's invention relates to an expandable intraluminal graft for use within a body passageway or duct and, more particularly, expandable intraluminal vascular grafts which are particularly useful for repairing blood vessels narrowed or occluded by disease; and a method and apparatus for implanting expandable intraluminal grafts. Figures 1A and 1B show an expandable intraluminal vascular graft or prosthesis 70 (i.e., a stent) which may be utilized not only in connection with an expandable intraluminal vascular graft for expanding partially occluded segments of a blood vessel, or body passageway, but may also be utilized for many other purposes as an expandable prosthesis for many other types of body passageways.

Figures 3 and 4 of Schatz show the expandable intraluminal vascular graft 70 disposed or mounted upon a catheter 83 having an expandable, inflatable portion 84 associated therewith. Catheter 83 includes means for mounting and retaining 85 the

expandable intraluminal vascular graft 70 on the expandable, inflatable portion 84 of catheter 83. The mounting and retaining means 85 comprises retainer ring members 86 disposed on the catheter 83 adjacent the expandable inflatable portion 84 of catheter 83 and a retainer ring member 86 disposed adjacent each end 72, 73 of the expandable intraluminal vascular graft 70. The retainer ring member 86 adjacent the leading tip 87 of catheter 83 slopes upwardly and away from catheter tip 87 in order to protect and retain graft 70 as it is inserted into the lumen 81 of body passageway 80. The remaining retainer ring member 86 slopes downwardly away from tip 87 of catheter 83, to insure easy removal of catheter 83 from body passageway 80. After the expandable intraluminal graft 70 has been disposed upon the catheter 83, the graft 70 and catheter 83 are inserted within a body passageway 80 by catheterization of the body passageway 80 in a conventional manner.

In a conventional manner, the catheter 83 and graft 70 are delivered to the desired location within the body passageway 80, whereat it is desired to expand the lumen 81 of body passageway 80 via intraluminal graft 70. Graft, 70 is then controllably expanded and deformed by controllably expanding the expandable, inflatable portion 84 of catheter 83, whereby the graft, 70 is expanded and deformed radially, outwardly into contact with the body passageway 80, as shown in Figure 4. The expandable, inflatable portion of catheter 83 may be a conventional angioplasty balloon 88. After

the desired expansion and deformation of graft, 70 has been accomplished, angioplasty balloon 88 may be collapsed, or deflated, and the catheter 83 may be removed in a conventional manner from body passageway 80. Schatz teaches (column 8, lines 40-45) that if desired, catheter 83, having graft 70 disposed thereon, may be initially encased in a sheath 89 which is pulled away from the graft 70, prior to expansion of the prosthesis, or graft, 70.

Still with reference to Figures 3 and 4, it should be noted that graft 70 initially has a first predetermined, collapsed diameter d in order to permit the insertion of the graft 70 into the body passageway 80. When it is desired to implant graft 70 within a body passageway 80 the graft 70 is controllably expanded and deformed to a second diameter d' and the second, expanded diameter d' is variable and determined by the internal diameter of the body passageway 80, as shown in Figure 4, and by the amount of expansion of the inflatable portion 84 of catheter 83. Accordingly, the expanded and deformed graft 70 upon deflation of angioplasty balloon 88 will not be able to migrate from the desired location within the body passageway 80, nor will the expansion of the graft 70 be likely to cause a rupture of the body passageway 80.

The appellants argue throughout the briefs that step (c) of independent claims 25 and 29 is not disclosed by Schatz.² The examiner believes (answer, pp. 4-5) that step (c) of independent claims 25 and 29 is inherent in Schatz since (1) there is no such thing as a pure or total vacuum so there should be some residual air however infinitesimal the amount in the balloon and (2) a balloon must be expanded to some degree in order to engage the stent (i.e., graft 70) for deployment.

To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently. In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). As stated in In re Oelrich, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981) (quoting Hansgirk v. Kemmer, 102 F.2d 212, 214, 40 USPQ 665, 667 (CCPA 1939)) (internal citations omitted):

Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient.

Thus, a prior art reference may anticipate when the claim limitation or limitations not expressly found in that reference are nonetheless inherent in it. See In re Oelrich, 666

² Step (c) of independent claim 25 recites "partially inflating the balloon to secure the stent onto the balloon." Step (c) of independent claim 29 recites "partially expanding the expandable member of the delivery catheter to secure the stent onto the expandable member."

F.2d at 581, 212 USPQ at 326; Verdegaal Bros., Inc. v. Union Oil Co., 814 F.2d 628, 630, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates. See In re King, 801 F.2d 1324, 1326, 231 USPQ 136, 138 (Fed. Cir. 1986). However, inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. See Mehl/Biophile Int'l Corp. v. Milgraum, 192 F.3d 1362, 1365, 52 USPQ2d 1303, 1305-06 (Fed. Cir. 1999); Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1946-47 (Fed. Cir. 1999).³

We agree with the appellants that step (c) of independent claims 25 and 29 is not disclosed by Schatz since, contrary to the examiner's belief, step (c) of independent claims 25 and 29 is not inherent in Schatz. In that regard, the examiner has not adequately explained why the step of "partially inflating the balloon to secure the stent onto the balloon" (independent claim 25) or the step of "partially expanding the expandable member of the delivery catheter to secure the stent onto the expandable member" (independent claim 25) is the natural result flowing from the disclosed operation of Schatz's graft and catheter. Even assuming that the examiner is correct that there is some residual air in Schatz's balloon 88 while the catheter 83 and graft 70

³ In this regard, we note that a rejection of independent claims 25 and 29 under 35 U.S.C. § 103 on the basis that step (c) would have been obvious at the time the invention was made to a person of ordinary skill in the art is not before us in this appeal.

are being moved along the body passageway 80 into position, we fail to see, and the examiner has not explained, how that residual air would be considered to be a partial inflation of the balloon to secure the graft onto the balloon. Likewise, while balloon 88 of Schatz must be expanded to some degree in order to engage the graft 70 for deployment, we fail to see, and the examiner has not explained, how that fact would be a partial inflation of the balloon to secure the graft onto the balloon rather than being the expanding and deploying step set forth in step (f) of independent claim 25 and 29.

For the reasons set forth above, all the limitations of claims 25 and 29 are not disclosed in Schatz. Accordingly, the decision of the examiner to reject claims 25 and 29, and claims 26, 30 and 31 dependent thereon, under 35 U.S.C. § 102(e) is reversed.

The obviousness rejection

We will not sustain the rejection of claims 27, 28 and 32 to 37 under 35 U.S.C. § 103 as being unpatentable over Schatz in view of Hillstead.

In the rejection of claims 27, 28 and 32 to 37 under 35 U.S.C. § 103 the examiner concluded (final rejection, p. 3) that in view of Hillstead's teaching of an elastic sleeve positioned about and around a balloon catheter that

[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to take the invention of Schatz and utilize a "sleeve" as a

means for retaining the stent to the balloon catheter because it could be easily removed without injuring the vessel.^[4]

Even if the examiner were correct that the limitations of claims 27, 28 and 32 to 37 would have been obvious at the time the invention was made to a person of ordinary skill in the art, this would not result in the claimed subject matter since all the limitations of claims 25 and 29 are not disclosed in Schatz for the reasons set forth above. In addition, the examiner has not set forth any reasoning or rationale as to why the limitations of claims 25 and 29 not disclosed in Schatz would have been obvious at the time the invention was made to a person of ordinary skill in the art. Accordingly, the decision of the examiner to reject claims 27, 28 and 32 to 37 under 35 U.S.C. § 103 is reversed.

⁴ Claims 27, 28 and 33 to 35 recite a sleeve positioned around the stent. Hillstead's sleeve 40 is not positioned around the stent 32. However, Schatz's sheath 89 is positioned around the graft 70 as shown in Figure 3. Claims 32, 36 and 37 do not recite any sleeve and it is unclear to us how the examiner is rejecting these claims since the examiner has not even asserting that the subject matter of these claims would have been obvious at the time the invention was made to a person of ordinary skill in the art.

CONCLUSION

To summarize, the decision of the examiner to reject claims 25, 26 and 29 to 31 under 35 U.S.C. § 102(e) is reversed and the decision of the examiner to reject claims 27, 28 and 32 to 37 under 35 U.S.C. § 103 is reversed.

REVERSED

NEAL E. ABRAMS
Administrative Patent Judge

LAWRENCE J. STAAB
Administrative Patent Judge

JEFFREY V. NASE
Administrative Patent Judge

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FULWIDER PATTON LEE & UTECHT, LLP
HOWARD HUGHES CENTER
6060 CENTER DRIVE
TENTH FLOOR
LOS ANGELES, CA 90045

JVN/jg